



April 6, 2009

NIOSH Docket Office
Docket 109
Robert A. Taft Laboratories
MS-C34
4676 Columbia Parkway
Cincinnati, OH 45226

RE: NIOSH Docket RIN 0920-AA04

Docket Officer:

The American Industrial Hygiene Association (AIHA) expresses its appreciation to the Department of Health and Human Services and the National Institute for Occupational Safety and Health (NIOSH) for the opportunity to comment on the proposed rule on Quality Assurance Requirements for Respirators proposed in the *Federal Register* on December 10, 2008. AIHA appreciates the opportunity to have our comments received and considered.

As the premier association of occupational and environmental health and safety professionals, AIHA members serve on the front line of worker health and safety. AIHA members, as well as employees and employers, rely on federal and state rules and regulations to improve the health and safety of the workplace and protect employees. We applaud the institute for taking this step in proposing this rule.

Comments on this proposed rule were compiled by the AIHA Respiratory Protection Committee whose members provide a forum for exchanging ideas and information on control of exposure to toxic and irritating substances and oxygen-deficient atmospheres through the use of respiratory protection.

AIHA appreciates the opportunity to work with NIOSH to help achieve the mutual goal of protecting American workers and we look forward to further opportunities to work with the institute on this and similar issues and regulatory priorities.

If AIHA can be of any further assistance, please contact me. Thank you.

Sincerely,

Lindsay E. Booher, CIH, CSP
AIHA President

**AIHA
Respiratory Protection Committee
Comments on
DEPARTMENT OF HEALTH AND HUMAN SERVICES
42 CFR PART 84
Quality Assurance Requirements for Respirators
Notice of Proposed Rulemaking**

NIOSH Docket RIN: 0920-AA04

The AIHA Respiratory Protection Committee strongly endorses the proposed use of upgraded quality management systems standards for approval of respiratory protection equipment. The experience of members who administer large respiratory protection programs is that manufacturers who have ISO 9001 or similar quality programs are able to address and respond to quality problems better than manufacturer's who rely on their own internal, inwardly focused, programs. By actively seeking customer feedback on quality concerns and working these concerns into a systematic program of continuous improvements, both the reliability of the equipment and it's suitability to meet worker needs is enhanced.

The following are additional specific comments for the consideration of NIOSH:

1. Noting that the current 42CFR84 quality assurance (QA) standards were effective on March 30, 1974 in 30CFR11 and placed into 42CFR84 without change, the Respiratory Protection Committee encourages NIOSH to maintain QA standards and practices that are updated to the current revision of ISO 9001 Quality Management System standards. Reference to the ISO 9001, 2000 3rd edition is outdated.
2. The Respiratory Protection Committee supports NIOSH replacing the current product inspection sampling requirements contained in 42CFR84 which are more than 40 years old with quality assessment requirements appropriate to the variety of present day quality management approaches and appropriate to a consumer-oriented statistical weighting of "producer and consumer risks".
3. The Respiratory Protection Committee agrees with a requirement of timely reporting and response to complaints of a particularly serious nature that potentially involves health endangerment.
4. The Respiratory Protection Committee supports an effective program of manufacturing site and product audits to assure compliance with 42CFR84 requirements.

These proposed requirements achieve a greater degree of standardization of quality practices among manufacturers of respiratory protective devices.